Remarks

Claim 1 has been amended to reflect the elected SEQ ID NO: 5. Claims 2-22 have been cancelled without prejudice to or disclaimer of the underlying subject matter, and new claims 23 through 28 have been added. Support for the foregoing claim amendments and new claims may be found throughout the specification, for example at page 73, lines 1-15, in the sequence listing, and in the original claims. The specification has been amended in response to the Office Communication mailed June 2, 2004 to remove alleged embedded hyperlinks. No new matter enters by these amendments. Upon entry of the foregoing amendments, claims 1 and 23-28 are pending in the application.

1. Response to Election/Restriction

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants further acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants submit that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide

sequences to be claimed in a single application." (M.P.E.P., 8th ed., rev. 1, February 2003, Section 803.04). The MPEP further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Finally, the Examiner asserts that Applicants "argue that SEQ ID NO: 5 is not patentably distinct from the other sequences listed in claim 2, for example." Office Action at page 3. Applicants respectfully assert that no such argument has been made. Rather, Applicants maintain their position that each nucleotide sequence is *not necessarily* a patentably distinct species.

Although Applicants disagree with the election requirement of a single nucleotide sequence, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 5.

2. Lack of Utility Rejections under 35 U.S.C. §§ 101 and 112, First Paragraph

A. Rejection under 35 U.S.C. § 101

Claims 1 and 2 stand rejected under 35 U.S.C. § 101 paragraph, for allegedly lacking "patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility." Office Action at page 4. Claim 2 has been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claim 1.

The Examiner acknowledges that the specification describes "a plethora of enzymes with their corresponding activities." *Id.* However, the Examiner contends that the "disclosed uses are generally applicable to broad classes of this subject matter," and the specification "lacks any specific or substantial connection disclosure between the elected SEQ ID NO: 5 and any of the described enzymes." *Id.* Applicants respectfully disagree with these assertions.

It is well established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. For example, the claimed nucleic acid molecules are useful for isolating a variety of agronomically significant genes, acquiring molecular markers, promoters, transcriptional regulatory elements, identifying polymorphisms, in expression assays, etc. *See, e.g.*, page 96, *et. seq.*, under the heading "Uses of the Agents of the Invention." The claimed nucleic acid molecules also find use in the reduction of endogenous protein expression through cosuppression and antisense applications. *See, e.g.* page 144, line 3 through page 146, line 14.

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and

characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed nucleic acid molecules possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating that "the disclosed uses are generally applicable to broad classes of this subject matter." Office Action at page 4. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner also argues that the claimed nucleic acid molecules lack utility because "further characterization of the claimed subject matter would be required to identify or reasonably confirm a 'real world' use." Office Action at page 4. The Examiner argues that the claimed nucleic acid molecules lack utility because he "does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. *Id.* However, Applicants respectfully submit that the specification provides ample connection between SEQ ID NO: 5 and the disclosed enzymes. For example, the specification describes the isolation of nucleic acid molecules from young maize seedlings (V8 plant development stage) for the production of the SATMON009 cDNA library. *See, e.g.,* specification at page 193, line 14, through page 194, line 7. As such, these sequences may function in plant growth, quality, yield, and could also serve as links in important metabolic, developmental, and catabolic

pathways. The specification also describes, as noted by the Examiner, that the sequence of the enzyme encoded by SEQ ID NO: 5 is similar to sequences of other ribulose-bisphosphate carboxylase enzymes. *See, e.g.*, Table A, page 254. Other portions of the specification describe that SEQ ID NO: 5 encodes a ribulose-bisphosphate carboxylase enzyme (*see, e.g.*, specification at page 26, lines 9-17, page 79, lines 20-22, and Table A, page 254). Applicants respectfully submit that such disclosure provides a sufficient connection between SEQ ID NO: 5 and the disclosed encoded enzyme, ribulose-bisphosphate carboxylase.

The Examiner asserts, however, that "one skilled in the art would have reason to doubt that sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence." Office Action at page 5. The Examiner has provided references supporting only the general controversy in the art regarding homology, but has not provided any support for the proposition that the claimed nucleic acid molecules would not work for the recited utilities; or that one skilled in the art would doubt that the claimed nucleic acid molecules would work for the utilities disclosed in the present specification. A broad assertion of "unpredictability" in the art is not sufficient to reject the claimed invention for lack of utility.

Applicants further note that it is standard practice to use nucleic acids of known sequence (*e.g.*, SEQ ID NO: 5) to perform gene expression analysis using methods such as microarray technology. Knowing that an RNA corresponding to the claimed nucleic acid molecule is expressed under certain conditions or in certain tissues or at certain

levels is in itself useful. For example, such information is useful to detect and compare expression changes in tissue samples taken from organisms grown under different conditions, *e.g.*, drought stress, cold stress, exposure to pathogens, or exposure to chemical compounds. SEQ ID NO: 5 might be differentially expressed, for example, under one or more growth conditions that tend to induce expression changes of ribulose-bisphosphate carboxylase. *See, e.g.,* specification at page 49, line 12 through page 54, line 10. Microarrays allow rapid, simultaneous expression analysis of thousands of sequences, and thus, informative *patterns* of expression are derived from the microarray expression data. For at least these reasons, Applicants respectfully submit that expression analysis is a **use** of SEQ ID NO: 5 in a real world context. Applicants further submit that the specification teaches one of skill in the art how to use SEQ ID NO: 5 for this purpose. *See, e.g.,* specification at page 117, line 12 through page 118, line 15 (describing use of SEQ ID NO: 5 for microarray analysis of gene expression profiles).

The Examiner has provided no evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utilities and, as such, has not met the burden of challenging the disclosed utilities. *Cf. In re Swartz,* 232 F.3d 862, 863, 56 U.S.P.Q.2d 1703, 1704 (Fed. Cir. 2000); *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 U.S.P.Q. 48, 51 (C.C.P.A. 1981)). 462, 108 U.S.P.Q. 321, 325 (C.C.P.A. 1956). Furthermore, Applicants do not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons,* 340 F.2d 974, 978, 144 U.S.P.Q. 351, 354 (C.C.P.A. 1965). Instead, evidence will be sufficient if, considered as a whole, it leads a person of

ordinary skill in the art to conclude that the asserted utility is more likely than not true. MPEP § 2164.07. Applicants have met this burden.

Surprisingly, credibility has not been assessed. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 752 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); M.P.E.P. § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here the Examiner has not even attempted to meet this burden. Thus, the lack of challenge of utilities suggests that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the

presently asserted utilities. Consequently, the rejection of claim 1 is improper. Applicants respectfully request reconsideration and withdrawal of this rejection.

B. Rejection Under 35 U.S.C. § 112, 1st Paragraph: Enablement

The Examiner has rejected claims 1 and 2 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Office Action at page 6. Claim 2 has been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claim 1. Applicants respectfully disagree and assert that the rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

3. Rejections under 35 U.S.C. § 112, Second Paragraph

Claim 1 has been rejected under 35 U.S.C. § 112, second paragraph as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Office Action at page 6.

Claim 1 is allegedly indefinite in the recitation of the phrase "fragment thereof" because "a fragment without definition as to its metes and bounds could be as small as a single nucleotide or a short polymer fragment etc." *Id.* Applicants respectfully disagree. A grammatically consistent interpretation of the claim as amended would relate the phrase "fragment thereof" back to the phrase "ribulose-bisphosphate carboxylase enzyme" directly preceding it. Thus, the skilled artisan would understand that the

claimed nucleic acid molecule encodes a protein or fragment thereof and no lower limit for the fragment size need be recited. Based on the foregoing, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

4. Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1 and 2 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being described in the specification "in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at page 7. Applicants respectfully disagree. Claim 2 has been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claim 1.

The Examiner does not dispute that Applicants have possession of and have adequately described SEQ ID NO: 5. *Id.* However, the Examiner argues that Applicants have allegedly not described the claimed nucleic acid molecules. The basis for the Examiner's rejection is that "claims 1 and 2 are directed to encompass gene sequences, allelic variants with SEQ ID NO: 5 via the fragments of claim 1 as well as flanking variants included withint [sic] claim 2." *Id.* Apparently, the Examiner argues that "[t]he specification provides insufficient written description to support the genus encompassed by the claims." *Id.* Applicants respectfully disagree.

This argument flies in the face of the existing patent jurisprudence. It is well-established law that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80

U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of "unspecified ingredients" is that they are not specified or described. The Examiner attempts to turn the legal meaning of "comprising" on its head by requiring Applicants to describe every hypothetical claim element. Applicants need only describe the claimed invention, and have done so in the present application.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventor actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventor had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of nucleic acid molecules comprising nucleic acid molecules that encode a maize or soybean carbon assimilation pathway enzyme or fragment thereof, and SEQ ID NO: 5, and therefore, the claimed invention.

Applicant's present disclosure not only provides the nucleic acid sequences required by the claims (*e.g.*, ribulose-bisphosphate and SEQ ID NO: 5), but further

describes that the claimed nucleic acid molecules may include the recited sequence with additional sequences, for example, vectors comprising the claimed nucleic acid molecules (*see, e.g.,* specification at page 125, line 12 through page 134, line 18) and binary artificial chromosomes (BIBACs) and other systems that may be used to introduce the claimed nucleic acid molecules into a host cell (*see, e.g.,* specification at page 134, lines 19 through page 135, line 4). The specification also describes, for example, nucleic acid molecules comprising single nucleotide polymorphisms (SNPs) and methods to identify sequences containing them (*see, e.g.,* specification at page 83, line 18 through page 85, line 10), methods for identifying nucleic acid molecules comprising promoter regions and other regulatory elements (*see, e.g.,* specification at page 98, lines 1-13), nucleic acid molecules comprising nucleic acid sequences having conservative substitutions (*see, e.g.,* specification at page 76, line 13 through page 77, line 21), fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 91, lines 7-19), plant and other homologue proteins and nucleic acid molecules (*see, e.g.,* specification at page 91, lines 20 through page 92 line 8), site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 120, line 22 through page 122, line 6), and references describing the construction, manipulation and isolation of nucleic acid macromolecules (*see, e.g.,* specification at page 179, lines 11-18). Despite the numerous variations described for the claimed nucleic acid molecules in the present specification, the Examiner maintains that "the species specifically disclosed are not representative of the genus because the genus is highly variant." Office Action at page 8.

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description. For example, Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 5, and complements and variants thereof. The respective common structural feature (*e.g.*, the nucleotide sequences of SEQ ID NO: 5 and their complements) is shared by every nucleic acid molecule in the claimed genera, and it distinguishes the members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 5, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 5. If a nucleic acid molecule does not contain SEQ ID NO: 5, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 5 or it does not.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, pending claim 1 is supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed. Reconsideration and withdrawal are respectfully requested.

5. Rejections under 35 U.S.C. § 102

Claim 1 stands rejected under 35 U.S.C. § 102(b) as allegedly being "clearly anticipated by the 1990 Sigma Chemical Catalog disclosure of either of products O 4128, O 8628, or O 8878." (Sigma). Applicants respectfully traverse this rejection.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). In the present application, claim 1 is directed to isolated nucleic acid molecules encoding maize or soybean carbon assimilation pathway enzymes. Whatever else the Sigma catalog discloses, it does not disclose a maize or soybean carbon assimilation enzyme. The Examiner has applied an untenable interpretation of the claims to cover small fragments of the specifically claimed nucleic acid molecule and thus concludes that the claim is anticipated by the cited reference. Office Action at page 8. A grammatically consistent interpretation of claim 1, as amended, would relate the phrase "or fragment thereof" back to the phrase "ribulose-bisphosphate carboxylase enzyme" directly preceding it.

As such, the presently amended claims are not anticipated by Sigma cited by the Examiner. Whatever Sigma teaches, it does not disclose a maize or soybean ribulose-bisphosphate carboxylase enzyme or SEQ ID NO: 5. Absent a teaching of each and every element of the claim, the reference cited by the Examiner does not anticipate claim 1 and the rejection should be reversed.

Accordingly, for at least the foregoing reasons, the rejection of claim 1 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

6. Claim Objections and Informalities

A. Claims Objections

Claims 1 and 2 are objected to as "being inclusive of subject matter directed to sequences other than the elected SEQ ID NO: 5." Office Action at page 9. The above amendments to the claims are believed to overcome this objection. Applicants respectfully request reconsideration and withdrawal of this objection.

B. Informalities Objections

The specification has been objected to for purportedly containing "embedded hyperlink and/or other form of browser-executable code." Office Action at page 9

The purpose of the requirement that hyperlinks or other forms of browser executable code be removed from the specification is so that on the United States Patent and Trademark Office website, one cannot click on the hyperlink and be transported to another, potentially commercial, website. This requirement does not exclude the listing of a website that is not present as a hyperlink.

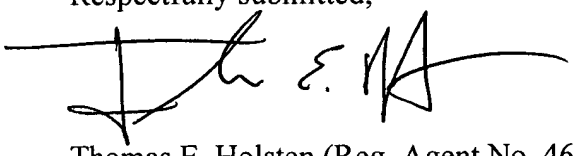
Applicants have amended the specification to delete the phrase "http://" (instead listing the websites using the format www-websitename.html). Therefore, the citation of a website in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application.

In light of these remarks and amendments, Applicants respectfully request withdrawal of this objection to the specification.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



Thomas E. Holsten (Reg. Agent No. 46,098)
Holly Logue Prutz (Reg. Atty No. 47,755)
David R. Marsh (Reg. Atty No. 41,408)
ARNOLD & PORTER LLP

Date: July 2, 2004

Correspondence Address:
MONSANTO COMPANY
Patent Department
800 N. Lindbergh Blvd.
Mailzone E2NA
St. Louis MO 63167
(314) 694-3602 telephone
(314) 694-1671 facsimile